UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *EX REL.* CHARLES BATES, III and CRAIG PATRICK PLAINTIFFS, *v.* KYPHON, INC. DEFENDANT	CIVIL ACTION NO. 05-CV-6568CJS(F) **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** JURY TRIAL DEMANDED

COMPLAINT

Plaintiff and qui tam Charles M. Bates and Craig Patrick, through their attorneys Phillips & Cohen LLP and Chamberlain & D'Amanda, for their Complaint against Kyphon, Inc. allege as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent statements, records, and claims made and caused to be made by the defendant and/or its agents and employees in violation of the Federal False Claims Act, 31 U.S.C. §3729 et seq., ("the FCA" or "the Act").

2. This qui tam case is brought against defendant Kyphon, Inc. for systematically knowingly presenting, or causing to be presented, false or fraudulent claims to Medicare for services and related costs when they knew they were not entitled to payment for such services.

As a direct result of defendant's improper practices, the federal Treasury has been damaged in substantial amount.

3. The FCA was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub.L. 99-562, 100 Stat. 3153. Congress enacted the 1986 amendments to enhance and modernize the Government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government frauds to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf.

4. The Act provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 up to $11,000 for each such claim, plus three times the amount of the damages sustained by the federal Government.

5. The Act allows any person having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time). Based on these provisions, qui tam plaintiffs and relators Charles Bates and Craig Patrick, seek through this action to recover damages and civil penalties arising from the defendant's knowing fraud on the U.S. Government.

II. PARTIES

6. Plaintiff/relator Charles Bates III, is a resident of Birmingham, Alabama. Mr. Bates was employed by Kyphon, Inc. as a Spine Consultant from August 2001 through June 2002 and a Regional Sales Manager from July 2002 through July 2005. Prior to being employed by Kyphon, Mr. Bates worked in sales positions at Guidant, Inc., Baxter Healthcare Corporation, and Merit Medical Systems, Inc.

7. Plaintiff/relator Craig Patrick is a resident of Hudson, Wisconsin. Mr. Patrick is a current employee of Kyphon. Mr. Patrick was hired in August 2003 as a reimbursement manager and continues in that position today. Craig Patrick is an expert in the managed care and sales arenas with extensive experience working with Medicare, Medicaid, and large third party payers. Mr. Patrick has been involved with sales and reimbursement within the healthcare industry for over ten years.

8. Kyphon Inc. is a medical device company focused on the design, manufacture and marketing of instruments used in minimally invasive therapies by surgeons and their patients for the treatment and restoration of spinal anatomy. Kyphon is currently marketing surgical tools that use its proprietary balloon technologies for the repair of spinal fractures. Kyphon markets its products through sales representatives in the United States, and through a combination of sales representatives, distributors and agents in its international markets. The Company is headquartered in Sunnyvale, California, incorporated in Delaware, and has subsidiaries in many of the major countries in Europe, and in Canada and Japan.

III. JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. §1331 and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

10. This Court has personal jurisdiction over the defendant pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the defendant has at least minimum contacts with the United States. Moreover, the defendant can be found in, resides in or transacts or has transacted business in the Western District of New York.

11. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because the defendant can be found in, and transacts or has transacted business in the Western District of New York. Specifically, defendant has marketed its products to Buffalo General Hospital, Millard Fillmore Gates Hospital, Roswell Park Cancer Institute, and Sisters of Charity Hospital. These hospitals have purchased products and performed Kyphoplasty procedures as described in this Complaint.

IV. BACKGROUND

A. THE MEDICARE PROGRAM

12. Medicare is a federally-funded health insurance program primarily benefitting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. The Medicare program has two parts. Medicare Part A ("Part A"), the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services and post-hospital nursing facility care.

Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of physicians' services, certain pharmaceutical products, diagnostic tests and other medical services not covered by Part A.

13. The Medicare program is administered through the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

14. Much of the daily administration and operation of the Medicare program is managed through contracts with private insurance companies that operate as fiscal intermediaries. Fiscal Intermediaries are responsible for accepting claims for reimbursements under Medicare Part A (and some claims under Part B), and making payments for such claims. "Medicare Carriers" are responsible for accepting and paying claims for reimbursements under Medicare Part B.

15. Reimbursement of drugs, devices, or services is dependent upon public and private payer policies governing the coverage of those items or services, and the coding used to identify those items or services. Policies define coverages under what circumstances an item or service will be paid. Codes specify diagnoses, or products and services provided to beneficiaries. Providers are paid in exchange for providing products and services to beneficiaries.

16. The Centers for Medicare & Medicaid Services (CMS) administers Medicare, the nation's largest health insurance program, provides health insurance to people age 65 and over, those who have end-stage kidney failure, and certain people with disabilities. Medicare Part A (Hospital Insurance) covers hospital inpatient stays. Medicare Part B (Medical Insurance) covers

physician services. Medicare beneficiaries do not have to pay for Part A benefits, but they need to pay a monthly premium for Part B benefits.

17. Inpatient services include room and board and any services and procedures performed while the patient was admitted to the hospital. Providers use codes to define what services are rendered, and payers in turn use those codes to determine payment. Different settings of care have different payment systems. In the hospital inpatient setting where Medicare is the payer, the payment amount is determined by the Diagnosis-Related Groups, or DRGs. DRGs are a prospective payment system, meaning clinically similar diagnoses and/or procedure codes map to a DRG which then has a pre-determined reimbursement rate. (Clinically similar diagnoses and procedures naturally have similar resource utilization.)

18. A DRG's pre-determined reimbursement rate is paid to the hospital regardless of how long the patient is admitted or the number of services provided. Physician services provided while the patient is admitted are billed and reimbursed separately from DRGs. Physician services are reimbursed through a payment system called Resource-Based Relative Value Scale (RBRVS). In the RBRVS system, payments for services are determined by the resource costs needed to provide them. The cost of providing each service is divided into three components: physician work, practice expense, and professional liability insurance (malpractice). Payments are calculated by multiplying the combined costs of a service by a conversion factor (a monetary amount that is determined by CMS). Payments are also adjusted for geographical differences in resource costs. RBRVS payments are based on Current Procedural Terminology (CPT) codes.

B THE ANTI-KICKBACK STATUTE

19. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

20. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, medical device companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend products that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a company that has as one of its purposes inducement of a physician to perform additional procedures using the company's products.

21. Violation of the Anti-Kickback statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7).

C, THE DISEASE OF OSTEOPOROSIS

22. Osteoporosis is a disease in which bones become fragile and are more likely to break. National Osteoporosis Foundation (www.nof.org). If not prevented or if left untreated, osteoporosis can progress painlessly until a bone breaks. These broken bones, also known as fractures, occur typically in the hip, spine, and wrist.

23. When a bone in the spine collapses, it is called a vertebral compression fracture (VCF). These fractures happen most commonly in the thoracic spine (the middle portion of the spine), particularly in the lower vertebrae of the thoracic spine.

24. Spinal or vertebral body compression fractures (VCFs) can have serious consequences, including loss of height, severe back pain, and deformity.

25. According to the FDA, Osteoporosis causes more than 700,000 spinal fractures each year in the United States. This is more than twice the annual number of hip fracture cases, according to the National Osteoporosis Foundation.

26. According to Kyphon's website, spinal fractures may collapse acutely while others collapse progressively over time. If left untreated, one fracture can lead to subsequent fractures, often resulting in a condition called kyphosis. Kyphosis is signified by the "dowager's hump", or rounded back. Kyphosis compresses the chest and abdominal cavity with many potential health consequences. (www.kyphon.com)

27. Osteoporosis affects more women than men. After menopause, women are especially vulnerable to bone loss. More than one-fourth of women over age 65 will develop a vertebral fracture due to osteoporosis. Older people suffering from compression fractures tend to

become less mobile, and decreased mobility accelerates bone loss. High doses of pain medication, especially narcotic drugs, further limit functional ability.

28. Traditionally, fractures of the spine were treated conservatively with weeks of immobilization (bed rest) with bracing and drugs for the pain. Now there are several procedures to treat these fractures.

D. VERTEBROPLASTY

29. According to a public information web site developed and funded by the American College of Radiology and the Radiological Society of North America, Vertebroplasty is an image-guided, minimally invasive, nonsurgical therapy used to strengthen a broken vertebra (spinal bone) that has been weakened by osteoporosis or, less commonly, cancer. (www.radiologyinfo.org). According to the web site, Vertebroplasty can increase the patient's functional abilities, allow a return to the previous level of activity, and prevent further vertebral collapse. It is usually successful at alleviating the pain caused by a compression fracture. The web site states that vertebroplasty is often performed on an outpatient basis and is accomplished by injecting an orthopedic cement mixture through a needle into the fractured bone.

30. During Vertebroplasty the patient is sedated and receives a local anesthetic to numb the skin and the muscles near the spinal fracture. Intravenous antibiotics may also be administered to prevent infection. Through a small incision and guided by a fluoroscope, a hollow needle is passed through the spinal muscles until its tip is precisely positioned within the fractured vertebra.

31. A cement mixture including polymethylmethacrylate (PMMA), barium powder and a solvent is then injected. The cement mixture resembles toothpaste or epoxy. A physician

monitors the entire procedure on a fluoroscopy imaging screen and make sure that the cement mixture does not back up into the spinal canal.

32. Medical-grade cement hardens quickly, over the next 10 to 20 minutes. A CT scan may be performed at the end of the procedure to check the distribution of the cement. The longest part of the vertebroplasty procedure involves setting up the equipment and making sure the needle is perfectly positioned in the collapsed vertebra.

33. The vertebroplasty procedure usually takes less than two hours (longer if more than one site is being treated). Although patients are not be allowed to drive after the procedure, they can go home with an adult, if the distance is short. Otherwise, an overnight stay at a nearby hotel is advised. According to the American College of Radiology and the Radiological Society of North America web site, hospitalization is required only if the patient is unusually frail, has no one to help them at home, or requires further monitoring following the procedure.

34. Vertebroplasty is highly effective because after osteoporosis has made bones very porous, the cement fills the spaces and strengthens the bone so it is less likely to fracture again. After vertebroplasty, the cement stabilizes the fracture, which is thought to provide the pain relief. Patients begin regaining mobility within 24 hours and are usually able to reduce, or even eliminate, their pain medication.

35. Vertebroplasty is often performed on patients too elderly or frail to tolerate open spinal surgery, or with bones too weak for surgical spinal repair. Patients with vertebral damage due to a malignant tumor may sometimes benefit from vertebroplasty. In rare cases, it can be used in younger patients whose osteoporosis is caused by long-term steroid treatment or a metabolic disorder. Typically, vertebroplasty is recommended after simpler treatments—such as

bedrest, a back brace or pain medication—have been ineffective, or once medications have begun to cause other problems, such as stomach ulcers. Vertebroplasty can be performed right away in patients who have severe pain requiring hospitalization or conditions limiting bedrest and medications.

E. KYPHOPLASTY

36. Like Vertebroplasty, Balloon Kyphoplasty is a minimally invasive, orthopedic treatment that stabilizes a spinal fracture. The difference between Kyphoplasty and Vertebroplasty is the use of a balloon during the Kyphoplasty to create a cavity prior to introducing the bone cement.

37. In Kyphoplasty, the surgeon creates a small pathway into the fractured bone. A small, orthopedic balloon is guided through the instrument into the vertebra. The incision site is approximately 1 cm in length. Next the balloon is inflated in an attempt to raise the collapsed vertebra and return it to its normal position. Once the vertebra is in the correct position, the balloon is deflated and removed. This process creates a void (cavity) within the vertebral body.

38. The cavity is filled with a bone cement to support the surrounding bone and prevent further collapse. The cement forms an internal cast that holds the vertebra in place. Generally, the procedure is done on both sides of the vertebral body. Balloon Kyphoplasty typically takes one hour per fracture and the patient is observed for several hours afterward (some patients may require an overnight hospital stay). The procedure can be done using either local or general anesthesia; the surgeon will determine the most appropriate method, based on the patient's overall condition.

39. According to Kyphon, the ability to compact cancellous bone and create a cavity reduces the potential for extravertebral cement leakage during balloon kyphoplasty. The low complication rate is also related to the way in which viscous bone cement is delivered into a cavity under fine manual control. In other words, Kyphoplasty is a safer procedure than Vertebroplasty.

V. ALLEGATIONS

40. Kyphon has aggressively marketed Kyphoplasty as an Inpatient procedure to induce doctors and hospitals to purchase their products. In addition, Kyphon actively encourages doctors and hospitals to perform unnecessary biopsies to further increase reimbursement. Kyphon has a pattern and practice of giving free products to hospitals to induce them to purchase more products.

41. According to Kyphon Reimbursement materials, Medicare is the single largest payer of Kyphon products, paying for 85 to 90 percent of procedures performed.

42. Kyphon was founded in 1994 and operations commenced in September 1996. In January 1999, the company initiated limited direct sales of its first commercial products to several major medical centers. By May 2000, it had commenced full commercial introduction in the United States.

43. Currently there are over 4,500 orthopaedic surgeons, neurosurgeons, interventional radiologists and interventional neuroradiologists in the United States who specialize in treating the spine and perform Balloon Kyphoplasty. Over 175,000 fractures in 150,000 patients worldwide have been treated with Balloon Kyphoplasty to date.

44. In 2000, slightly more than 1,500 Kyphoplasty procedures were performed in the United States. In 2004 this number increased to over 48,000. It is estimated that 60,000 Kyphoplasty procedures will be performed in 2005.

45. At Kyphon, Relator Bates managed sales during this period of rapid expansion and worked with other Regional Sales Managers, Area Directors, V.P. of Sales, as well as Marketing and Reimbursement staff to implement and develop corporate strategies, maintain aggressive growth, and manage profitability of their respective regions.

46. Mr. Bates was also responsible for developing relationships with key surgeons in the region, managing surgeon education and training, and coordinating reimbursement initiatives. Mr. Bates was given an award for achieving his sales goals in eight consecutive quarters. Mr. Bates was also a Spine Consultant/Field Sales Trainer for Kyphon. In addition, Mr. Bates was the First local sales representative in this area for the pre-IPO surgical spine company. Responsibilities included developing the markets in Alabama and the Florida panhandle.

47. Mr. Bates's duties included, but were not limited to recruiting, training and promoting new surgeons. Mr. Bates was also responsible for establishing new accounts with all hospitals which including working with hospitals and physicians on coding and reimbursement questions, educating referring physicians and marketing the local surgeon "champions". Business in Mr. Bates's territory grew from $16,000 per month to over $200,000 per month in seven months.

48. A current employee, Relator Patrick's responsibilities include developing and executing strategic plans to improve coverage and reimbursement of Kyphoplasty. In addition,

he works directly with medical directors of Medicare carriers and private payers to ensure positive policy and reimbursement for Kyphoplasty. Mr. Patrick also handles large key accounts within the U.S. to gain further acceptance of Kyphoplasty from a reimbursement perspective, including hospitals and large health systems. Mr. Patrick supports the field sales group with direct account contact to clear reimbursement hurdles as well as arranges for surgeon reimbursement, training and champion development.

49. Usually a company trying to break into the market competes with other companies for market share. The situation at Kyphon is unique in that there is no direct competition for Kyphoplasty because it is a patented procedure. The challenge for Kyphon is educating and training doctors not only on the physical procedure, but convincing doctors and hospital personnel to follow reimbursement strategies to increase profitability of Kyphoplasty.

50. According to internal reports from Kyphon sales representatives, by and far, the biggest challenges to selling Kyphon's products to perform Kyphoplasty are poor reimbursement as an outpatient procedure and trying to convince doctors to perform Kyphoplasty as an inpatient procedure. However, Kyphon has made it clear to reimbursement personnel, including Mr. Patrick, that they will not lower the price of their product and reduce their large profit margins.

A. INPATIENT PROCEDURE

51. The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. Factors to be considered when making the decision to admit patients to the hospital include such things as 1) the severity of the signs and symptoms exhibited by the patient, 2) the medical

predictability of something adverse happening to the patient, 3) the need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and 4) the availability of diagnostic procedures at the time when and at the location where the patient presents. Hospital Manual, Ch. II, §210 Covered Inpatient Hospital Services.

52. When a patient with a known diagnosis enters a hospital for a specific minor surgical procedure that is expected to keep him in the hospital for only a few hours (less than 24), he is considered an outpatient for coverage purposes. Id.

53. As with Vertebroplasty, the majority of Kyphoplasty patients do not need to remain in the hospital overnight. Kyphon is committed to convincing doctors as well as hospitals that the opposite is true.

54. It is important that Kyphon convince hospitals that Kyphoplasty needs to be performed as an inpatient procedure. When a doctor wants to do new procedure at a hospital, he has to get credentialed by the hospital credentialing committee. The hospital credentialing committee, in order to approve the procedure, investigates the procedure, makes sure it is FDA approved and explores reimbursement for the procedure. If it appears that it is a procedure that will cost the hospital money, many times they will not approve the procedure.

55. If Kyphoplasty is performed as an inpatient procedure, patients are admitted for an overnight stay at the hospital and the hospital will be paid under the DRG. The hospital will be reimbursed for Kyphoplasty under DRG 233 (Musculoskeletal System and Connective

Tissue or Procedures **with** complications or co-morbidities) and 234 (Musculoskeletal System and Connective Tissue or Procedures **without** complications or co-morbidities.)

56. According to Kyphon's CEO Richard Mott, as of October 2003, under DRG's 233 and 234 hospitals were being paid approximately $6,000 (DRG 234) to approaching $10,000 (DRG 233) depending on geography.

57. If the doctor performs a biopsy during the Kyphoplasty, the hospital may be reimbursed under DRG 216 (Biopsies of musculoskeletal system connective tissue). Average reimbursement for DRG 216 would increase approximately $500 more than DRG 233.

58. Kyphoplasty used to be primarily performed by orthopedic surgeons and neurosurgeons. However, the number of interventional radiologists (IR's) and interventional neuroradiologists (INR's) performing kyphoplasty is increasing. Kyphon did not initially market to IRs and INRs because they do not admit large numbers of patients to the hospital on a regular basis. IRs and INRs primarily perform outpatient procedures, especially with Vertebroplasty which is almost entirely done in an outpatient setting.

59. Kyphon claims that there are fewer complications during Kyphoplasty than Vertebroplasty. It does not make sense that doctors perform a procedure with fewer complications as an inpatient procedure and do vertebroplasty, with more risk of complications, on an outpatient basis.

60. Mr. Patrick is aware of entire radiologist groups, such as St. Lukes in Milwaukee, that perform each and every kyphoplasty as an inpatient procedure. Dr. Paul Minor, the head of the department of St. Lukes told a group of radiologists during physician training that St. Lukes admits Kyphoplasty patients and keeps them overnight for reimbursement purposes. Dr. Paul Minor was a paid speaker of Kyphon at the time.

61. One HCA hospital was very resistant to doing kyphoplasty because they said it would be medicare fraud to do it on an inpatient basis. In a meeting at an HCA hospital in Nashville, a Dr. Cruz stated to hospital administration officials that he admitted the Kyphoplasty patients so the hospital would make money on the procedure. The hospital said that he could no longer do the procedure there. Phil Foster, a Kyphon Reimbursement Manager and Brad Guess, a Kyphon Regional Manager were present at the time.

62. In another example, Dr. Mark Myers, a doctor that has performed more Kyphoplasty procedures than any other doctor in Minnesota, admits most of his patients to the hospital triggering reimbursement under the DRG. Most of Dr. Myers's patients are only in the hospital for one day. Other radiologists have commented to Kyphon Sales Rep Chris Dudec that they believe what Dr. Myers is doing is fraud. Chris Dudec replaced a Sales Rep named Joel Criner. Physicians have also explained to Mr. Dudec that many were put off by Mr. Criner's aggressive position about admitting the patients to obtain reimbursement under the DRG.

63. Dr. Mark Meyers is on Kyphon's faculty and a speaker for the company. Dr. Meyers prepared a powerpoint presentation in which he claims that Kyphon is a "sexier procedure " with a much lower complication rate of 1 percent for Kyphoplasty versus 7.5 percent for Vertebroplasty.

64. Kyphon sales representatives and reimbursement managers visited with hospital coders to explain how they needed to bill these procedures for maximum reimbursement. Hospital coders were told to make sure that the codes they used tracked to DRG 233 and DRG 234. Specifically, sales representatives were instructed to tell the doctor to make sure to find and document other co-morbidities so they could get DRG 233 and make more money for the hospital that if it is reimbursed under DRG 234. .

65. In an effort to further bill Medicare for their procedure, since approximately 2001, Kyphon sales representatives also marketed to physicians that if they performed a biopsy during the procedure, it would be paid under DRG 216 which would provide even more reimbursement than under DRG 233.

66. Kyphon sales representatives encouraged doctors to Biopsy every patient, even if there was nothing to indicate the patient needed a biopsy. In February 2003, Kyphon released their "Bone Biopsy Device," a disposable, stainless steel tube and rod that can be used to take biopsy samples of bone for further evaluation.

67. According to Mr. Bates, Kyphon Sales Representatives marketed the Bone Biopsy Device as a way to make biopsies during Kyphoplasty legitimate. Immediately after the release, sales representatives were told to tell doctors to use the tool to "cover their tracks." The tool costs $110 but at the time increased reimbursement by approximately $500.

68. Representatives stated that the tool served a dual purposed, it provided a better biopsy and covered the doctor on the reimbursement side. In addition, the doctors were told that if they performed a biopsy, they did not have to worry about finding a co-morbidity to make sure they were reimbursed under DRG 233, since DRG 216 paid more reimbursement. The sales reps were also told to make sure that the coders picked up the biopsy to get to DRG 216.

69. Medicare will only reimburse for a biopsy if it is medically necessary. However, Kyphon's strategy was to get the doctors to perform a biopsy on every patient. Sales representatives were told to try to get the Bone Biopsy Devise listed on the card of the doctors preferences "for surgeons that want to use it on every case."

70. In early 2003, sales representative David Munro stated that his biggest issue regarding HCA hospitals was reimbursement but that "the bone biopsy has saved the day." According to internal documents, Mr Munro explained, "I worked a long time with the OR, CFO and Medical Records trying to get to the right DRG (233) for the hospital to approve the surgeons use of the IBT. The use of the new bone biopsy device allowed the use of DRG 216 with the 3M software. The two HCA hospitals (Ocala Regional and Tallahassee Community) are excited about reimbursement and want more cases."

71. In early 2005 Medicare reduced reimbursement under DRG 216. On February 2, 2005, Rich Pilon, Director of Reimbursement, sent an email to all of the Sales and Reimbursement employees at Kyphon announcing, "[t]his is to inform you that there has been a change regarding DRG 216. The new relative weight for DRG 216 has been lowered to 1.8966. As a frame of reference, DRG 233 has a relative weight of 1.9542." According to Mr. Patrick, Mr. Pilon's intention was to discourage the sales force from continuing the practice of promoting biopsies to increase reimbursement. Mr. Pilon was chastised by Kyphon Management for sending the email.

72. Prior to this, Kyphon was trying to sell as many biopsy devices as possible. Kyphon's Vice-President of Sales, Regional Managers and Area Directors hold a weekly conference call. According to Mr. Bates, Kyphon announced on one of these calls that they are tracking sales of the bone biopsy device and there was a contest to see who could sell the most product.

73. Some private insurers reimburse doctors at a higher rate than Medicare. Because of this, some doctors perform Kyphoplasty as an outpatient procedure for private pay patients, but perform Kyphoplasty on all Medicare patients as an inpatient procedure. Dr.

Sammons of Huntsville, Alabama performs approximately thirty cases per quarter and selects inpatient or outpatient based reimbursement.

B. OUTPATIENT PROCEDURE

74. The biggest obstacle in getting doctors to perform Kyphoplasty as an outpatient procedure is the price Kyphon charges for materials compared to the price reimbursed by Medicare. Rather than lower the price for their product, Kyphon has looked for creative ways to game the system and maximize reimbursement for the doctors and hospitals.

75. For reimbursement, doctors are told by Sales Reps to use CPT code 22899, which is an unlisted code for procedures on the spine. Kyphoplasty does not currently have its own CPT code.

76. Surgeons were resistant to using 22899 because unlisted codes automatically get flagged for review by the fiscal intermediaries. When this was encountered Kyphon Sales representatives would facilitate that the doctors or their office staff learn "alternative methods" of billing to increase reimbursement.

77. When Mr. Bates began at Kyphon and had reimbursement questions, he was told by his boss, Brad Paddock, a Regional Manager, to call another sales representative, Dave Monro. Mr. Paddock described Mr. Monro as "someone who knows how to make things happen."

78. According to Mr. Bates, Mr. Monro would tell the doctors how to bill for the procedure, but he would also direct doctors to contact other doctors to see how they billed for the procedure. Mr. Monro and another sales rep, David Ager, had all of their surgeons using "open reduction codes."

79. When a doctor billed for Kyphoplasty under a CPT code for "open treatment and/or reduction of vertebral fracture..." the reimbursement increased significantly. Sales representatives would explain to the doctor that this is acceptable because they are "reducing" the fracture. This was the most common method for increasing reimbursement to the doctors. In training presentations, Kyphon describes the "open treatment and/or reduction" codes as "potentially related" CPT codes.

80. The "open reduction" codes are still be used by some surgeons, although some Medicare carriers have gotten wise for the most part and are not reimbursing doctors for Kyphoplasty under those CPT codes. In addition, many carriers as a result of the number of biopsies performed during Kyphoplasty have issued guidelines stating that they consider it to be part of the procedure and that it should not be billed separately.

81. In the beginning the open/reduction codes were used almost exclusively with the surgeons who were early adaptors in the Chicago area. This was heavily encouraged by Sales representative Roger Yapp who was eventually promoted to Regional Sales Manager. Mr. Yapp is no longer with the company.

82. Interestingly, some surgeons stopped performing Kyphoplasty when they could no longer bill under the "open reduction" codes. Kyphon was well aware of the fact that doctors were billing with these inappropriate codes and encouraged the behavior.

83. During a reimbursment talk in Missouri, a Kyphon faculty member interrupted and "corrected" Mr. Patrick during a presentation and told all of the physicians present to bill the procedure under the "open" CPT code.

84. Kyphoplasty is not an "open" procedure, but is a percutaneous procedure. Percutaneous means "through the skin."

85. According to Mr. Patrick, Mary K. Hailey, Kyphon's Vice President of Reimbursement, has been in a constant battle with the sales force over such practices. Ms. Hailey was against using the "Open Reduction Codes" for reimbursement, but was continually ignored by the Sales Force.

86. Jeffrey Schultz, a sales representative for the Mid-Atlantic region announced in a report that, "[i]t's no secret that some surgeons in the area have become "creative" in the way they bill for use of the KyphX System."

87. A few years ago, Kyphon's Reimbursement Department was informed by physicians that the hospitals were claiming that they were losing money on Kyphoplasty procedures. Kyphon created what is known as the Economic Support Model to essentially call the hospitals' bluff as to their losing money. The Economic support model shows the exact reimbursement that the hospital will receive for each procedure under the DRG. This model was not designed for marketing purposes, but sales reps were given copies of it to show the hospitals exactly how much they could make if they did this procedure. Eventually the Sales force was told to return their copies of the economic sales model.

C. KICKBACKS

88. In order to get doctors to train to perform Kyphoplasty, Kyphon sales representatives commit to bringing patients to the doctors. In order to bring business to the doctor, sales representatives go to primary care physicians and other doctors to educate them about the procedure. Sales representatives also talk to seniors groups and take out newspaper ads advertising the doctors services. Eventually, sales representatives were told that they could only advertise the procedure if they listed at least three doctors from the area in the ad.

1. SPINE EDUCATION SPECIALISTS (SES)

89. In early 2003, Kyphon launched their Spine Education Specialist (SES) program. According to Kyphon, the SES pilot program was designed to help Kyphon understand how best to assist in the facilitation of spine surgeon's education of primary care physicians. According to Richard Mott, President and CEO of Kyphon, the SES program was not designed to generate incremental sales growth initially. However, based on the results of the SES program and experience, Mr. Mott stated that it is the belief of the company that a national SES program would enhance Kyphon revenue growth in the future.

90. According to Anthony J. Recupero Vice President of Sales at Kyphon, some of the initial criteria in determining where to place SES's were 1) states with high surgeon reimbursement, 2) territories with a large number active surgeons, 3) a significant number of top prescribing primary care physicians, 4) tenured spine consultants with excellent physician relationships, and 5) areas with extremely high potential for growth.

91. The SES program became a program to enhance revenue growth for Kyphon and Kyphon-trained doctors. The SES reps were paid by the company to mine for patients for doctors as a reward for performing the procedure. The compensation packages for SES reps were designed to spur referrals for Kyphoplasty, setting quotas and paying SES reps a commission based on how many patients they referred for the procedure.

92. During Kyphon's 2005 Annual Sales Conference, a radiologist spoke at the meeting stating that his practice was happy to have the SES there because it was like having an extra employee. This was videotaped although it is unknown if the tape still exists.

93. In order to help the SES reps cultivate patients, they were given a high subscriber spreadsheet listing 19,000 prescribers of osteoporosis medications. This was a

mailing list that was originally used to send marketing information. The spreadsheet had been changed to list each rep with doctors that they should contact to try to get business.

94. On April 12, 2005, Craig Patrick sent Mary Hailey, Richard Pilon, and all reimbursement managers a document explaining, *inter alia*, why it was a problem for Kyphon to be paying to generate referrals for doctors.

95. On April 13, 2005, Richard Pilon forwarded the document to David Shaw, corporate counsel for Kyphon. Shortly after Mr. Patrick sent this memo, it was announced that the SES group would be disbanded and the company would turn them into spine consultants or let them go.

96. Mr. Patrick also warned about other areas of concern such as Kyphon's marketing of physicians. Kyphon would send out marketing newsletters on behalf of doctors and pay for print ads for individual doctors. In addition, Kyphon would have reps write letters to primary care physicians in the area on behalf of the doctor. Other reps would have the doctor issue the letter on the doctors letterhead, then Kyphon would do all the printing, stuffing the envelopes, and mailing of the letters.

97. In addition, Kyphon paid doctors as speakers, sometimes as much as $1500 per event. .

2. FREE SAMPLES

98. Kyphon frequently gives free product to induce hospitals to perform Kyphoplasty at their facility.

99. At another HCA hospital in Nashville, Tennessee, the hospital was not going to perform Kyphoplasty at all because of poor reimbursement for it as an outpatient procedure. The hospital did not feel that they could do it as an inpatient only procedure. The sales

representative told the hospital that Kyphon would give them free supplies for every outpatient procedure.

100. Sales representatives give hospitals free samples of products as an inducement to buy Kyphon products. Sales representatives were not limited to how many sample "kits" they could give away, so long as they tracked their samples. Sales representatives would ask hospitals for "No Charge Purchase Orders" so the sales representatives could later show the hospital how much free product the hospital received and how much money they saved using free products.

101. In addition, sales representatives would make deals with the hospital where if they bought ten kits, Kyphon would give them one free. According to Mr. Bates, the sales representatives did not tell the hospitals not to bill Medicare for the free products that were distributed, but it was understood that the free products were to offset the price of the other products.

102. On October 18, 2005, Relator Patrick spent the morning with Tracy Wirtz, a Kyphon Spine Consultant based out of Minneapolis. Mr. Patrick and Ms. Wirtz visited Gundersen Lutheran Medical Center (GLMC) in La Crosse WI. Ms. Wirtz informed Mr. Patrick that the account is tough on price, "so in order to get them to do more cases we insure all cases are one level". According to Ms. Wirtz, Kyphon gives GLMC free kits whenever it is medically necessary to do anything more than one level of Kyphoplasty. Kyphon charges GLMC approximately $3,500 for a first fracture kit. The other kits are provided at no charge, but it is understood by all involved that the hospital is expected to bill the government for the free kits.

103. According to Mr. Patrick, Ms. Wirtz is not aware that she is doing anything inappropriate and is following Kyphon's management guidance and Kyphon internal guidelines.

In addition, the arrangement with GLMC was in effect before Ms. Wirtz was assigned the account.

104. When Mr. Patrick asked if this had helped sales Ms. Wirtz replied, "of course". GLMC did forty-four cases in the 3rd Quarter of 2005, and over 80% were billed to Medicare. The reasoning for the free product is that if Kyphon does not provide them, the hospitals will do Vertebroplasty instead, which is a much less expensive procedure that has very similar results to Kyphoplasty. Relator Patrick has heard this situation many times and believes that the company has a regular pattern and practice of giving free product as an incentive to do more and more cases.

COUNT I

False Claims Act

31 U.S.C. §3729(a)(1)

105. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1-104.

106. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729 *et seq.*

107. Through the acts described above, defendant Kyphon, Inc. knowingly presented, or caused to be presented, false or fraudulent claims, to the United States Government, in order to obtain government reimbursement for health care services provided under Medicare, Medicaid, and other Federal programs.

108. As a result of these false claims, the United States has been damaged and continues to be damaged, in an amount yet to be determined.

COUNT II

False Claims Act

31 U.S.C. §3729(a)(2)

109. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1-104.

110. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729 *et seq.*

111. Through the acts described above, defendant Kyphon, Inc. has knowingly made, used and caused to be made and used false records and statements to get false or fraudulent claims paid in order to obtain government reimbursement for health care services provided under Medicare, Medicaid and other Federal programs.

112. As a result of these false claims, the United States has been damaged and continues to be damaged, in an amount yet to be determined.

COUNT III

False Claims Act

31 U.S.C. §3729(a)(7)

113. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1-104.

114. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729 *et seq.*

115. Through the acts described above, defendant Kyphon, Inc. has knowingly failed to disclose to the United States material facts in order to obtain government reimbursement for health care services provided under Medicare, Medicaid and other federal programs.

116. As a result of these false claims, the United States has been damaged and continues to be damaged, in an amount yet to be determined.

Prayer

WHEREFORE, plaintiff prays for judgment against the defendant as follows:

1. that Defendant cease and desist from violating 31 U.S.C. §3729 et seq.;

2. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that plaintiff be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

4. that plaintiff be awarded all costs of this action, including attorneys' fees and expenses; and

5. that the United States and plaintiff recover such other and further relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, plaintiff hereby demands a trial by jury.

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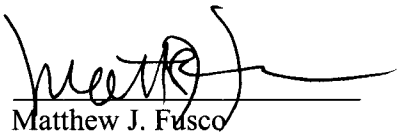
By: 

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Charles Bates and Craig Patrick
October 26, 2005